Attorney Docket No.: 24852-501 CIP2

Express Mail Label No.: EV942366951US Date of Deposit: May 10, 2007

<u>AMENDMENT</u>

Amendments to the Claims:

Please amend the claims as follows, without prejudice:

In the Claims:

1. (Currently Amended) A method of <u>orally</u> treating cutaneous T-cell lymphoma in a subject, said method comprising the step of administering to the subject an effective amount a total daily dose of 200-600 mg of a pharmaceutical composition comprising suberoylanilide hydroxamic acid (SAHA) or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

and a pharmaceutically acceptable carrier or diluent, wherein the amount of SAHA is effective to treat cutaneous T-cell lymphoma in said subject.

2. (Withdrawn) A method of treating cutaneous T-cell lymphoma in a subject, said method comprising the step of administering to the subject an effective amount of a pharmaceutical composition comprising pyroxamide or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

and a pharmaceutically acceptable carrier or diluent, wherein the amount of pyroxamide is effective to treat cutaneous T-cell lymphoma in said subject.

3. (Withdrawn) A method of treating cutaneous T-cell lymphoma in a subject, said method comprising the step of administering to the subject an effective amount of a

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pharmaceutical composition comprising a histone deacetylase inhibitor or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

wherein R₃ and R₄ are independently a substituted or unsubstituted, branched or unbranched alkyl, alkenyl, cycloalkyl, aryl, alkyloxy, aryloxy, aryloxy, arylalkyloxy, or pyridine group, cycloalkyl, aryl, aryloxy, arylalkyloxy, or pyridine group, or R₃ and R₄ bond together to form a piperidine group; R₂ is a hydroxylamino group; and n is an integer from 5 to 8, and a pharmaceutically acceptable carrier or diluent, wherein the amount of histone deacetylase inhibitor is effective to treat the cutaneous T-cell lymphoma in said subject.

4. (Withdrawn) A method of treating cutaneous T-cell lymphoma in a subject, said method comprising the step of administering to the subject an effective amount of a pharmaceutical composition comprising a histone deacetylase inhibitor or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

wherein R is a substituted or unsubstituted phenyl, piperidine, thiazole, 2-pyridine, 3-pyridine or 4-pyridine and n is an integer from 4 to 8, and a pharmaceutically acceptable carrier or diluent, wherein the amount of histone deacetylase inhibitor is effective to treat the cutaneous T-cell lymphoma in said subject.

5. (Withdrawn) A method of treating cutaneous T-cell lymphoma in a subject, said method comprising the step of administering to the subject an effective amount of a pharmaceutical composition comprising a histone deacetylase inhibitor or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

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$$R_1$$
 R_2
 $(CH_2)n$
 $NHOH$
 R_4

wherein A is an amide moiety, R₁ and R₂ are each selected from substituted or unsubstituted aryl (e.g., phenyl), arylalkyl (e.g., benzyl), naphthyl, pyridineamino, 9-purine-6-amino, thiazoleamino, aryloxy, arylalkyloxy, pyridyl, quinolinyl or isoquinolinyl; R₄ is hydrogen, a halogen, a phenyl or a cycloalkyl moiety and n is an integer from 3 to 10, and a pharmaceutically acceptable carrier or diluent, wherein the amount of histone deacetylase inhibitor is effective to treat the cutaneous T-cell lymphoma in said subject.

- 6. (Cancelled).
- 7. (Currently Amended) The method of claim 61, wherein said composition is contained within a gelatin capsule.
- 8. (Currently Amended) The method of claim 71, wherein said carrier or diluent is microcrystalline cellulose.
- 9. (Currently Amended) The method of claim <u>81</u>, <u>wherein said composition</u> further comprisesing sodium croscarmellose as a disintegrating agent.
- 10. (Currently Amended) The method of claim 91, wherein said composition further comprisesing magnesium stearate as a lubricant.
- 11. (Cancelled).
- 12. (Currently Amended) The method of claim 61, wherein said composition is administered once-daily, twice-daily or three times-daily.

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13. (Currently Amended) The method of claim 12, wherein said composition is administered once daily at a dose of about-200-600 mg.

- 14. (Currently Amended) The method of claim 12, wherein said composition is administered twice daily at a dose of about 200-400 mg.
- 15. (Currently Amended) The method of claim 12, wherein said composition is administered twice daily at a dose of about 200-400 mg intermittently.
- 16. (Previously Presented) The method of claim 15, wherein said composition is administered twice daily three to five days per week.
- 17. (Previously Presented) The method of claim 16, wherein said composition is administered twice daily three days a week.
- 18. (Currently Amended) The method of claim 17, wherein said composition is administered twice daily at a dose of about-200 mg, three days a week.
- 19. (Currently Amended) The method of claim 17, wherein said composition is administered twice daily at a dose of about-300 mg, three days a week.
- 20. (Withdrawn) The method of claim 2, wherein the pharmaceutical composition is administered orally.
- 21. (Withdrawn) The method of claim 20, wherein said composition is contained within a gelatin capsule.
- 22. (Withdrawn) The method of claim 21, wherein said carrier or diluent is microcrystalline cellulose.

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23. (Withdrawn) The method of claim 22, further comprising sodium croscarmellose as a disintegrating agent.

- 24. (Withdrawn) The method of claim 23, further comprising magnesium stearate as a lubricant.
- 25. (Withdrawn) The method of claim 2, wherein said composition is administered to the subject at a total daily dosage of between about 25-4000 mg/m².
- 26. (Withdrawn) The method of claim 20, wherein said composition is administered oncedaily, twice-daily or three times-daily.
- 27. (Withdrawn) The method of claim 26, wherein said composition is administered once daily at a dose of about 200-600 mg.
- 28. (Withdrawn) The method of claim 26, wherein said composition is administered twice daily at a dose of about 200-400 mg.
- 29. (Withdrawn) The method of claim 26, wherein said composition is administered twice daily at a dose of about 200-400 mg intermittently.
- 30. (Withdrawn) The method of claim 29, wherein said composition is administered twice daily three to five days per week.
- 31. (Withdrawn) The method of claim 30, wherein said composition is administered twice daily three days a week.
- 32. (Withdrawn) The method of claim 31, wherein said composition is administered twice daily at a dose of about 200 mg, three days a week.

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33. (Withdrawn) The method of claim 31, wherein said composition is administered twice daily at a dose of about 300 mg, three days a week.

34. (Currently Amended) A method of treating cutaneous T-cell lymphoma in a subject, which method comprises the step of <u>orally</u> administering to the subject a total daily dose of <u>about 800 200-600</u> mg of a pharmaceutical composition comprising suberoylanilide hydroxamic acid (SAHA)—or—a—pharmaceutically—acceptable—salt—or—hydrate—thereof, represented by the structure:

and a pharmaceutically acceptable carrier or diluent, wherein the cutaneous T-cell lymphoma in a subject is treated.

- 35. (Cancelled).
- 36. (Currently Amended) The method of claim 3534, wherein said composition is contained within a gelatin capsule.
- 37. (Previously Presented) The method of claim 36, wherein said carrier or diluent is microcrystalline cellulose.
- 38. (Currently Amended) The method of claim 37, wherein said composition further comprisesing sodium croscarmellose as a disintegrating agent.
- 39. (Currently Amended) The method of claim 38, wherein said composition further comprisesing magnesium stearate as a lubricant.
- 40. (Currently Amended) The method of claim <u>3534</u>, wherein said composition is administered once-daily, twice-daily or three times-daily.

- 41. (Currently Amended) The method of claim 40, wherein said composition is administered once daily at a dose of about-200-600 mg.
- 42. (Currently Amended) The method of claim 40, wherein said composition is administered twice daily at a dose of about 200-400 mg.
- 43. (Currently Amended) The method of claim 40, wherein said composition is administered twice daily at a dose of about 200-400 mg intermittently.
- 44. (Previously Presented) The method of claim 43, wherein said composition is administered twice daily three to five days per week.
- 45. (Previously Presented) The method of claim 44, wherein said composition is administered twice daily three days a week.
- 46. (Currently Amended) The method of claim 45, wherein said composition is administered twice daily at a dose of about 200 mg, three days a week.
- 47. (Currently Amended) The method of claim 45, wherein said composition is administered twice daily at a dose of about-300 mg, three days a week.
- 48. (Withdrawn) A method of treating peripheral T-cell lymphoma in a subject, said method comprising the step of administering to the subject an effective amount of a pharmaceutical composition comprising suberoylanilide hydroxamic acid (SAHA) or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

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and a pharmaceutically acceptable carrier or diluent, wherein the amount of SAHA is effective to treat the peripheral T-cell lymphoma in said subject.

49. (Withdrawn) A method of treating peripheral T-cell lymphoma in a subject, said method comprising the step of administering to the subject an effective amount of a pharmaceutical composition comprising pyroxamide or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

and a pharmaceutically acceptable carrier or diluent, wherein the amount of pyroxamide is effective to treat the peripheral T-cell lymphoma in said subject.

50. (Withdrawn) A method of treating peripheral T-cell lymphoma in a subject, said method comprising the step of administering to the subject an effective amount of a pharmaceutical composition comprising a histone deacetylase inhibitor or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

$$R_3$$
— N
 C — $(CH_2)n$ — C
 R_2

wherein R₃ and R₄ are independently a substituted or unsubstituted, branched or unbranched alkyl, alkenyl, cycloalkyl, aryl, alkyloxy, aryloxy, arylakyloxy, or pyridine group, cycloalkyl, aryl, aryloxy, arylakyloxy, or pyridine group, or R₃ and R₄ bond together to form a piperidine group; R₂ is a hydroxylamino group; and n is an integer from 5 to 8, and a pharmaceutically acceptable carrier or diluent, wherein the amount of the histone deacetylase inhibitor is effective to treat the peripheral T-cell lymphoma in said subject.

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51. (Withdrawn) A method of treating peripheral T-cell lymphoma in a subject, said method comprising the step of administering to the subject an effective amount of a pharmaceutical composition comprising a histone deacetylase inhibitor or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

wherein R is a substituted or unsubstituted phenyl, piperidine, thiazole, 2-pyridine, 3-pyridine or 4-pyridine and n is an integer from 4 to 8, and a pharmaceutically acceptable carrier or diluent, wherein the amount of the histone deacetylase inhibitor is effective to treat the peripheral T-cell lymphoma in said subject.

52. (Withdrawn) A method of treating peripheral T-cell lymphoma in a subject, said method comprising the step of administering to the subject an effective amount of a pharmaceutical composition comprising a histone deacetylase inhibitor or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

$$R_1$$
 R_2
 R_4
 R_4

wherein A is an amide moiety, R₁ and R₂ are each selected from substituted or unsubstituted aryl (e.g., phenyl), arylalkyl (e.g., benzyl), naphthyl, pyridineamino, 9-purine-6-amino, thiazoleamino, aryloxy, arylalkyloxy, pyridyl, quinolinyl or isoquinolinyl; R₄ is hydrogen, a halogen, a phenyl or a cycloalkyl moiety and n is an integer from 3 to 10, and a pharmaceutically acceptable carrier or diluent, wherein the amount of the histone deacetylase inhibitor is effective to treat the peripheral T-cell lymphoma in said subject.

53. (Withdrawn) The method of claim 48, wherein the pharmaceutical composition is administered orally.

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54. (Withdrawn) The method of claim 53, wherein said composition is contained within a gelatin capsule.

- 55. (Withdrawn) The method of claim 54, wherein said carrier or diluent is microcrystalline cellulose.
- 56. (Withdrawn) The method of claim 55, further comprising sodium croscarmellose as a disintegrating agent.
- 57. (Withdrawn) The method of claim 56, further comprising magnesium stearate as a lubricant.
- 58. (Withdrawn) The method of claim 48, wherein said composition is administered to the subject at a total daily dosage of between about 25-4000 mg/m².
- 59. (Withdrawn) The method of claim 53, wherein said composition is administered oncedaily, twice-daily or three times-daily.
- 60. (Withdrawn) The method of claim 53, wherein said composition is administered once daily at a dose of about 200-600 mg.
- 61. (Withdrawn) The method of claim 53, wherein said composition is administered twice daily at a dose of about 200-400 mg.
- 62. (Withdrawn) The method of claim 53, wherein said composition is administered twice daily at a dose of 200-400 mg intermittently.
- 63. (Withdrawn) The method of claim 62, wherein said composition is administered twice daily three to five days per week.

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64. (Withdrawn) The method of claim 63, wherein said composition is administered twice daily three days a week.

- 65. (Withdrawn) The method of claim 64, wherein said composition is administered twice daily at a dose of about 200 mg, three days a week.
- 66. (Withdrawn) The method of claim 64, wherein said composition is administered twice daily at a dose of about 300 mg, three days a week.
- 67. (Withdrawn) The method of claim 49, wherein the pharmaceutical composition is administered orally.
- 68. (Withdrawn) The method of claim 67, wherein said composition is contained within a gelatin capsule.
- 69. (Withdrawn) The method of claim 68, wherein said carrier or diluent is microcrystalline cellulose.
- 70. (Withdrawn) The method of claim 69, further comprising sodium croscarmellose as a disintegrating agent.
- 71. (Withdrawn) The method of claim 70, further comprising magnesium stearate as a lubricant.
- 72. (Withdrawn) The method of claim 49, wherein said composition is administered to the subject at a total daily dosage of between about 25-4000 mg/m².
- 73. (Withdrawn) The method of claim 67, wherein said composition is administered once-daily, twice-daily or three times-daily.

74. (Withdrawn) The method of claim 73, wherein said composition is administered once daily at a dose of about 200-600 mg.

- 75. (Withdrawn) The method of claim 73, wherein said composition is administered twice daily at a dose of about 200-400 mg.
- 76. (Withdrawn) The method of claim 75, wherein said composition is administered twice daily at a dose of about 200-400 mg intermittently.
- 77. (Withdrawn) The method of claim 76, wherein said composition is administered twice daily three to five days per week.
- 78. (Withdrawn) The method of claim 77, wherein said composition is administered twice daily three days a week.
- 79. (Withdrawn) The method of claim 78, wherein said composition is administered twice daily at a dose of about 200 mg, three days a week.
- 80. (Withdrawn) The method of claim 78, wherein said composition is administered twice daily at a dose of about 300 mg, three days a week.
- 81. (Withdrawn) A method of treating peripheral T-cell lymphoma in a subject, which method comprises the step of administering to the subject a total daily dose of up to about 800 mg of a pharmaceutical composition comprising suberoylanilide hydroxamic acid (SAHA) or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

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and a pharmaceutically acceptable carrier or diluent, wherein the peripheral T-cell lymphoma in a subject is treated.

- 82. (Withdrawn) The method of claim 81, wherein said composition is administered orally.
- 83. (Withdrawn) The method of claim 82, wherein said composition is contained within a gelatin capsule.
- 84. (Withdrawn) The method of claim 83, wherein said carrier or diluent is microcrystalline cellulose.
- 85. (Withdrawn) The method of claim 84, further comprising sodium croscarmellose as a disintegrating agent.
- 86. (Withdrawn) The method of claim 85, further comprising magnesium stearate as a lubricant.
- 87. (Withdrawn) The method of claim 82, wherein said composition is administered once-daily, twice-daily or three times-daily.
- 88. (Withdrawn) The method of claim 87, wherein said composition is administered once daily at a dose of about 200-600 mg.
- 89. (Withdrawn) The method of claim 87, wherein said composition is administered twice daily at a dose of about 200-400 mg.
- 90. (Withdrawn) The method of claim 87, wherein said composition is administered twice daily at a dose of about 200-400 mg intermittently.
- 91. (Withdrawn) The method of claim 90, wherein said composition is administered twice daily three to five days per week.

92. (Withdrawn) The method of claim 91, wherein said composition is administered twice daily three days a week.

- 93. (Withdrawn) The method of claim 92, wherein said composition is administered twice daily at a dose of about 200 mg, three days a week.
- 94. (Withdrawn) The method of claim 92, wherein said composition is administered twice daily at a dose of about 300 mg, three days a week.
- 95. (Withdrawn) A method of treating head and neck cancer in a subject, said method comprising the step of administering to the subject an effective amount of a pharmaceutical composition comprising suberoylanilide hydroxamic acid (SAHA) or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

and a pharmaceutically acceptable carrier or diluent, wherein the amount of SAHA is effective to treat the head and neck cancer in said subject.

96. (Withdrawn) A method of treating head and neck cancer in a subject, said method comprising the step of administering to the subject an effective amount of a pharmaceutical composition comprising pyroxamide or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

and a pharmaceutically acceptable carrier or diluent, wherein the amount of pyroxamide is effective to treat the head and neck cancer in said subject.

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97. (Withdrawn) A method of treating head and neck cancer in a subject, said method comprising the step of administering to the subject an effective amount of a pharmaceutical composition comprising a histone deacetylase inhibitor or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

$$R_3$$
 R_4 C $CH_2)n$ C R_2

wherein R₃ and R₄ are independently a substituted or unsubstituted, branched or unbranched alkyl, alkenyl, cycloalkyl, aryl, alkyloxy, aryloxy, arylakyloxy, or pyridine group, cycloalkyl, aryl, aryloxy, arylakyloxy, or pyridine group, or R₃ and R₄ bond together to form a piperidine group; R₂ is a hydroxylamino group; and n is an integer from 5 to 8, and a pharmaceutically acceptable carrier or diluent, wherein the amount of histone deacetylase inhibitor is effective to treat the head and neck cancer in said subject.

98. (Withdrawn) A method of treating head and neck cancer in a subject, which method comprising the step of administering to the subject an effective amount of a pharmaceutical composition comprising a histone deacetylase inhibitor or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

wherein R is a substituted or unsubstituted phenyl, piperidine, thiazole, 2-pyridine, 3-pyridine or 4-pyridine and n is an integer from 4 to 8, and a pharmaceutically acceptable carrier or diluent, wherein the amount of histone deacetylase inhibitor is effective to treat the head and neck cancer in said subject.

99. (Withdrawn) A method of treating head and neck cancer in a subject, said method comprising the step of administering to the subject an effective amount of a pharmaceutical composition comprising a histone deacetylase inhibitor or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

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$$R_1$$
 R_2
 R_4
 R_4

wherein A is an amide moiety, R₁ and R₂ are each selected from substituted or unsubstituted aryl (e.g., phenyl), arylalkyl (e.g., benzyl), naphthyl, pyridineamino, 9-purine-6-amino, thiazoleamino, aryloxy, arylalkyloxy, pyridyl, quinolinyl or isoquinolinyl; R₄ is hydrogen, a halogen, a phenyl or a cycloalkyl moiety and n is an integer from 3 to 10, and a pharmaceutically acceptable carrier or diluent, wherein the amount of histone deacetylase inhibitor is effective to treat the head and neck cancer in said subject.

- 100. (Withdrawn) The method of claim 95, wherein the pharmaceutical composition is administered orally.
- 101. (Withdrawn) The method of claim 100, wherein said composition is contained within a gelatin capsule.
- 102. (Withdrawn) The method of claim 101, wherein said carrier or diluent is microcrystalline cellulose.
- 103. (Withdrawn) The method of claim 102, further comprising sodium croscarmellose as a disintegrating agent.
- 104. (Withdrawn) The method of claim 103, further comprising magnesium stearate as a lubricant.
- 105. (Withdrawn) The method of claim 95, wherein said composition is administered to the subject at a total daily dosage of between about 25-4000 mg/m².

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106. (Withdrawn) The method of claim 100, wherein said composition is administered oncedaily, twice-daily or three times-daily.

- 107. (Withdrawn) The method of claim 106, wherein said composition is administered once daily at a dose of about 200-600 mg.
- 108. (Withdrawn) The method of claim 106, wherein said composition is administered twice daily at a dose of about 200-400 mg.
- 109. (Withdrawn) The method of claim 106, wherein said composition is administered twice daily at a dose of about 200-400 mg intermittently.
- 110. (Withdrawn) The method of claim 109, wherein said composition is administered twice daily three to five days per week.
- 111. (Withdrawn) The method of claim 110, wherein said composition is administered twice daily three days a week.
- 112. (Withdrawn) The method of claim 111, wherein said composition is administered twice daily at a dose of about 200 mg, three days a week.
- 113. (Withdrawn) The method of claim 111, wherein said composition is administered twice daily at a dose of about 300 mg, three days a week.
- 114. (Withdrawn) The method of claim 95, wherein the head and neck cancer is a squamous cell carcinoma.
- 115. (Withdrawn) The method of claim 96, wherein the pharmaceutical composition is administered orally.

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116. (Withdrawn) The method of claim 115, wherein said composition is contained within a gelatin capsule.

- 117. (Withdrawn) The method of claim 116, wherein said carrier or diluent is microcrystalline cellulose.
- 118. (Withdrawn) The method of claim 117, further comprising sodium croscarmellose as a disintegrating agent.
- 119. (Withdrawn) The method of claim 118, further comprising magnesium stearate as a lubricant.
- 120. (Withdrawn) The method of claim 96, wherein said composition is administered to the subject at a total daily dosage of between about 25-4000 mg/m².
- 121. (Withdrawn) The method of claim 115, wherein said composition is administered oncedaily, twice-daily or three times-daily.
- 122. (Withdrawn) The method of claim 121, wherein said composition is administered once daily at a dose of about 200-600 mg.
- 123. (Withdrawn) The method of claim 121, wherein said composition is administered twice daily at a dose of about 200-400 mg.
- 124. (Withdrawn) The method of claim 123, wherein said composition is administered twice daily at a dose of about 200-400 mg intermittently.
- 125. (Withdrawn) The method of claim 124, wherein said composition is administered twice daily three to five days per week.

126. (Withdrawn) The method of claim 125, wherein said composition is administered twice daily three days a week.

- 127. (Withdrawn) The method of claim 126, wherein said composition is administered twice daily at a dose of about 200 mg, three days a week.
- 128. (Withdrawn) The method of claim 126, wherein said composition is administered twice daily at a dose of about 300 mg, three days a week.
- 129. (Withdrawn) The method of claim 96, wherein the head and neck cancer is a squamous cell carcinoma.
- 130. (Withdrawn) A method of treating head and neck cancer in a subject, which method comprises the step of administering to the subject a total daily dose of up to about 800 mg of a pharmaceutical composition comprising suberoylanilide hydroxamic acid (SAHA) or a pharmaceutically acceptable salt or hydrate thereof, represented by the structure:

and a pharmaceutically acceptable carrier or diluent, wherein the head and neck cancer in a subject is treated.

- 131. (Withdrawn) The method of claim 130, wherein said composition is administered orally.
- 132. (Withdrawn) The method of claim 131, wherein said composition is contained within a gelatin capsule.
- 133. (Withdrawn) The method of claim 132, wherein said carrier or diluent is microcrystalline cellulose.

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134. (Withdrawn) The method of claim 133, further comprising sodium croscarmellose as a disintegrating agent.

- 135. (Withdrawn) The method of claim 134, further comprising magnesium stearate as a lubricant.
- 136. (Withdrawn) The method of claim 131, wherein said composition is administered oncedaily, twice-daily or three times-daily.
- 137. (Withdrawn) The method of claim 136, wherein said composition is administered once daily at a dose of about 200-600 mg.
- 138. (Withdrawn) The method of claim 136, wherein said composition is administered twice daily at a dose of about 200-400 mg.
- 139. (Withdrawn) The method of claim 136, wherein said composition is administered twice daily at a dose of about 200-400 mg intermittently.
- 140. (Withdrawn) The method of claim 139, wherein said composition is administered twice daily three to five days per week.
- 141. (Withdrawn) The method of claim 140, wherein said composition is administered twice daily three days a week.
- 142. (Withdrawn) The method of claim 141, wherein said composition is administered twice daily at a dose of about 200 mg, three days a week.
- 143. (Withdrawn) The method of claim 141, wherein said composition is administered twice daily at a dose of about 300 mg, three days a week.

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144. (Withdrawn) The method of claim 130, wherein the head and neck cancer is a squamous

cell carcinoma.

145. (Withdrawn) A method of selectively inducing terminal differentiation of neoplastic cells

in a subject and thereby inhibiting proliferation of such cells in said subject, said method

comprising the step of administering to said subject an effective amount of a

pharmaceutical composition comprising a HDAC inhibitor or a pharmaceutically

acceptable salt or hydrate thereof, and a pharmaceutically acceptable carrier or diluent,

wherein the composition is administered once, twice or three times daily at a total daily

dose of up to about 800 mg.

146. (Withdrawn) The method of claim 145, wherein the pharmaceutical composition is

administered orally.

147. (Withdrawn) The method of claim 146, wherein said composition is contained within a

gelatin capsule.

148. (Withdrawn) The method of claim 147, wherein said carrier or diluent is microcrystalline

cellulose.

149. (Withdrawn) The method of claim 148, further comprising sodium croscarmellose as a

disintegrating agent.

150. (Withdrawn) The method of claim 149, further comprising magnesium stearate as a

lubricant.

151. (Withdrawn) The method of claim 146, wherein said composition is administered once-

daily, twice-daily or three times-daily.

152. (Withdrawn) The method of claim 151, wherein said composition is administered once

daily at a dose of about 200-600 mg.

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153. (Withdrawn) The method of claim 151, wherein said composition is administered twice daily at a dose of about 200-400 mg.

- 154. (Withdrawn) The method of claim 151, wherein said composition is administered twice daily at a dose of about 200-400 mg intermittently.
- 155. (Withdrawn) The method of claim 154, wherein said composition is administered twice daily three to five days per week.
- 156. (Withdrawn) The method of claim 155, wherein said composition is administered twice daily three days a week.
- 157. (Withdrawn) The method of claim 156, wherein said composition is administered twice daily at a dose of about 200 mg, three days a week.
- 158. (Withdrawn) The method of claim 156, wherein said composition is administered twice daily at a dose of about 300 mg, three days a week.
- 159. (Withdrawn) The method of claim 151, wherein said composition is administered three times a day.
- 160. (Withdrawn) The method of claim 159, wherein said composition is administered three times-daily for two consecutive weeks, followed by one week without administration of said composition.
- 161. (Withdrawn) The method according to claim 145, wherein said HDAC inhibitor is suberoylanilide hydroxamic acid (SAHA):

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162. (Withdrawn) The method according to claim 145, wherein said HDAC inhibitor is pyroxamide, represented by the structure:

163. (Withdrawn) The method according to claim 145, wherein said HDAC inhibitor is represented by the structure:

$$R_3$$
— N
 C — $(CH_2)n$ — C
 R_2

wherein R₃ and R₄ are independently a substituted or unsubstituted, branched or unbranched alkyl, alkenyl, cycloalkyl, aryl, alkyloxy, aryloxy, arylalkyloxy, or pyridine group, cycloalkyl, aryl, aryloxy, arylalkyloxy, or pyridine group, or R₃ and R₄ bond together to form a piperidine group; R₂ is a hydroxylamino group; and n is an integer from 5 to 8.

164. (Withdrawn) The method according to claim 145, wherein said HDAC inhibitor is represented by the structure:

wherein R is a substituted or unsubstituted phenyl, piperidine, thiazole, 2-pyridine, 3-pyridine or 4-pyridine and n is an integer from 4 to 8.

165. (Withdrawn) The method according to claim 145, wherein said HDAC inhibitor is represented by the structure:

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$$R_1$$
 R_2
 $(CH_2)n$
 $NHOH$

wherein A is an amide moiety, R₁ and R₂ are each selected from substituted or unsubstituted aryl (e.g., phenyl), arylalkyl (e.g., benzyl), naphthyl, pyridineamino, 9-purine-6-amino, thiazoleamino, aryloxy, arylalkyloxy, pyridyl, quinolinyl or isoquinolinyl; R₄ is hydrogen, a halogen, a phenyl or a cycloalkyl moiety and n is an integer from 3 to 10.

- 166. (Withdrawn) A method of inducing differentiation of tumor cells in a subject having a tumor, said method comprising the step of administering to said subject an effective amount of a pharmaceutical composition comprising a HDAC inhibitor or a pharmaceutically acceptable salt or hydrate thereof, and a pharmaceutically acceptable carrier or diluent, wherein the composition is administered once, twice or three times daily at a total daily dose of up to about 800 mg.
- 167. (Withdrawn) The method according to claim 166, wherein the pharmaceutical composition is administered orally.
- 168. (Withdrawn) The method according to claim 167, wherein said composition is contained within a gelatin capsule.
- 169. (Withdrawn) The method according to claim 168, wherein said carrier or diluent is microcrystalline cellulose.
- 170. (Withdrawn) The method according to claim 169, further comprising sodium croscarmellose as a disintegrating agent.
- 171. (Withdrawn) The method according to claim 170, further comprising magnesium stearate as a lubricant.

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172. (Withdrawn) The method of claim 167, wherein said composition is administered oncedaily, twice-daily or three times-daily.

- 173. (Withdrawn) The method of claim 172, wherein said composition is administered once daily at a dose of about 200-600 mg.
- 174. (Withdrawn) The method of claim 172, wherein said composition is administered twice daily at a dose of about 200-400 mg.
- 175. (Withdrawn) The method of claim 172, wherein said composition is administered twice daily at a dose of about 200-400 mg intermittently.
- 176. (Withdrawn) The method of claim 175, wherein said composition is administered twice daily three to five days per week.
- 177. (Withdrawn) The method of claim 176, wherein said composition is administered twice daily three days a week.
- 178. (Withdrawn) The method of claim 177, wherein said composition is administered twice daily at a dose of about 200 mg, three days a week.
- 179. (Withdrawn) The method of claim 177, wherein said composition is administered twice daily at a dose of about 300 mg, three days a week.
- 180. (Withdrawn) The method of claim 172, wherein said composition is administered three times a day.
- 181. (Withdrawn) The method of claim 180, wherein said composition is administered three times-daily for two consecutive weeks, followed by one week without administration of said composition.

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182. (Withdrawn) The method according to claim 166, wherein said HDAC inhibitor is suberoylanilide hydroxamic acid (SAHA):

183. (Withdrawn) The method according to claim 166, wherein said HDAC inhibitor is pyroxamide, represented by the structure:

184. (Withdrawn) The method according to claim 166, wherein said HDAC inhibitor is represented by the structure:

$$R_3$$
— N
 C — $(CH_2)n$ — C
 R_2

wherein R₃ and R₄ are independently a substituted or unsubstituted, branched or unbranched alkyl, alkenyl, cycloalkyl, aryl, alkyloxy, aryloxy, arylalkyloxy, or pyridine group, cycloalkyl, aryl, aryloxy, arylalkyloxy, or pyridine group, or R₃ and R₄ bond together to form a piperidine group; R₂ is a hydroxylamino group; and n is an integer from 5 to 8.

185. (Withdrawn) The method according to claim 166, wherein said HDAC inhibitor is represented by the structure:

wherein R is a substituted or unsubstituted phenyl, piperidine, thiazole, 2-pyridine, 3-pyridine or 4-pyridine and n is an integer from 4 to 8.

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186. (Withdrawn) The method according to claim 166, wherein said HDAC inhibitor is represented by the structure:

$$R_1$$
 R_2
 $(CH_2)n$
 $NHOH$
 R_4

wherein A is an amide moiety, R₁ and R₂ are each selected from substituted or unsubstituted aryl (e.g., phenyl), arylalkyl (e.g., benzyl), naphthyl, pyridineamino, 9-purine-6-amino, thiazoleamino, aryloxy, arylalkyloxy, pyridyl, quinolinyl or isoquinolinyl; R₄ is hydrogen, a halogen, a phenyl or a cycloalkyl moiety and n is an integer from 3 to 10.

- 187. (Withdrawn) A method of selectively inducing cell growth arrest of neoplastic cells in a subject and thereby inhibiting proliferation of such cells in said subject, said method comprising the step of administering to said subject an effective amount of a pharmaceutical composition comprising a HDAC inhibitor or a pharmaceutically acceptable salt or hydrate thereof, and a pharmaceutically acceptable carrier or diluent, wherein the composition is administered once, twice or three times daily at a total daily dose of up to about 800 mg.
- 188. (Withdrawn) The method according to claim 187, wherein the pharmaceutical composition is administered orally.
- 189. (Withdrawn) The method according to claim 188, wherein said composition is contained within a gelatin capsule.
- 190. (Withdrawn) The method according to claim 189, wherein said carrier or diluent is microcrystalline cellulose.
- 191. (Withdrawn) The method according to claim 190, further comprising sodium croscarmellose as a disintegrating agent.

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192. (Withdrawn) The method according to claim 191, further comprising magnesium stearate as a lubricant.

- 193. (Withdrawn) The method of claim 188, wherein said composition is administered oncedaily, twice-daily or three times-daily.
- 194. (Withdrawn) The method of claim 193, wherein said composition is administered once daily at a dose of about 200-600 mg.
- 195. (Withdrawn) The method of claim 193, wherein said composition is administered twice daily at a dose of about 200-400 mg.
- 196. (Withdrawn) The method of claim 195, wherein said composition is administered twice daily at a dose of about 200-400 mg intermittently.
- 197. (Withdrawn) The method of claim 196, wherein said composition is administered twice daily three to five days per week.
- 198. (Withdrawn) The method of claim 197, wherein said composition is administered twice daily three days a week.
- 199. (Withdrawn) The method of claim 198, wherein said composition is administered twice daily at a dose of about 200 mg, three days a week.
- 200. (Withdrawn) The method of claim 198, wherein said composition is administered twice daily at a dose of about 300 mg, three days a week.
- 201. (Withdrawn) The method of claim 193, wherein said composition is administered three times a day.

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202. (Withdrawn) The method of claim 201, wherein said composition is administered three times-daily for two consecutive weeks, followed by one week without administration of said composition.

203. (Withdrawn) The method according to claim 187, wherein said HDAC inhibitor is suberoylanilide hydroxamic acid (SAHA):

204. (Withdrawn) The method according to claim 187, wherein said HDAC inhibitor is pyroxamide, represented by the structure:

205. (Withdrawn) The method according to claim 187, wherein said HDAC inhibitor is represented by the structure:

$$R_3$$
— N
 C — $(CH_2)n$ — C
 R_2

wherein R_3 and R_4 are independently a substituted or unsubstituted, branched or unbranched alkyl, alkenyl, cycloalkyl, aryl, alkyloxy, aryloxy, arylalkyloxy, or pyridine group, cycloalkyl, aryl, aryloxy, arylalkyloxy, or pyridine group, or R_3 and R_4 bond together to form a piperidine group; R_2 is a hydroxylamino group; and n is an integer from 5 to 8.

206. (Withdrawn) The method according to claim 187, wherein said HDAC inhibitor is represented by the structure:

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wherein R is a substituted or unsubstituted phenyl, piperidine, thiazole, 2-pyridine, 3-pyridine or 4-pyridine and n is an integer from 4 to 8.

207. (Withdrawn) The method according to claim 187, wherein said HDAC inhibitor is represented by the structure:

$$R_1$$
 N
 H
 R_2
 A
 $(CH_2)n$
 $NHOH$

wherein A is an amide moiety, R₁ and R₂ are each selected from substituted or unsubstituted aryl (e.g., phenyl), arylalkyl (e.g., benzyl), naphthyl, pyridineamino, 9-purine-6-amino, thiazoleamino, aryloxy, arylalkyloxy, pyridyl, quinolinyl or isoquinolinyl; R₄ is hydrogen, a halogen, a phenyl or a cycloalkyl moiety and n is an integer from 3 to 10.

- 208. (Withdrawn) A method of selectively inducing apoptosis of neoplastic cells in a subject and thereby inhibiting proliferation of such cells in said subject, said method comprising the step of administering to said subject an effective amount of a pharmaceutical composition comprising a HDAC inhibitor or a pharmaceutically acceptable salt or hydrate thereof, and a pharmaceutically acceptable carrier or diluent, wherein the composition is administered once, twice or three times daily at a total daily dose of up to about 800 mg.
- 209. (Withdrawn) The method according to claim 208, wherein the pharmaceutical composition is administered orally.
- 210. (Withdrawn) The method according to claim 209, wherein said composition is contained within a gelatin capsule.

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211. (Withdrawn) The method according to claim 210, wherein said carrier or diluent is microcrystalline cellulose.

- 212. (Withdrawn) The method according to claim 211, further comprising sodium croscarmellose as a disintegrating agent.
- 213. (Withdrawn) The method according to claim 212, further comprising magnesium stearate as a lubricant.
- 214. (Withdrawn) The method of claim 209, wherein said composition is administered oncedaily, twice-daily or three times-daily.
- 215. (Withdrawn) The method of claim 214, wherein said composition is administered once daily at a dose of about 200-600 mg.
- 216. (Withdrawn) The method of claim 214, wherein said composition is administered twice daily at a dose of about 200-400 mg.
- 217. (Withdrawn) The method of claim 216, wherein said composition is administered twice daily at a dose of about 200-400 mg intermittently.
- 218. (Withdrawn) The method of claim 217, wherein said composition is administered twice daily three to five days per week.
- 219. (Withdrawn) The method of claim 218, wherein said composition is administered twice daily three days a week.
- 220. (Withdrawn) The method of claim 219, wherein said composition is administered twice daily at a dose of about 200 mg, three days a week.

221. (Withdrawn) The method of claim 219, wherein said composition is administered twice daily at a dose of about 300 mg, three days a week.

- 222. (Withdrawn) The method of claim 214, wherein said composition is administered three times a day.
- 223. (Withdrawn) The method of claim 222, wherein said composition is administered three times-daily for two consecutive weeks, followed by one week without administration of said composition.
- 224. (Withdrawn) The method according to claim 208, wherein said HDAC inhibitor is suberoylanilide hydroxamic acid (SAHA):

225. (Withdrawn) The method according to claim 208, wherein said HDAC inhibitor is pyroxamide, represented by the structure:

226. (Withdrawn) The method according to claim 208, wherein said HDAC inhibitor is represented by the structure:

$$R_3$$
— N
 C — $(CH_2)n$ — C
 R_2

wherein R₃ and R₄ are independently a substituted or unsubstituted, branched or unbranched alkyl, alkenyl, cycloalkyl, aryl, alkyloxy, aryloxy, arylalkyloxy, or pyridine

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group, cycloalkyl, aryl, aryloxy, arylalkyloxy, or pyridine group, or R_3 and R_4 bond together to form a piperidine group; R_2 is a hydroxylamino group; and n is an integer from 5 to 8.

227. (Withdrawn) The method according to claim 208, wherein said HDAC inhibitor is represented by the structure:

wherein R is a substituted or unsubstituted phenyl, piperidine, thiazole, 2-pyridine, 3-pyridine or 4-pyridine and n is an integer from 4 to 8.

228. (Withdrawn) The method according to claim 208, wherein said HDAC inhibitor is represented by the structure:

$$R_1$$
 R_2
 $(CH_2)n$
 $NHOH$
 R_4

wherein A is an amide moiety, R₁ and R₂ are each selected from substituted or unsubstituted aryl (e.g., phenyl), arylalkyl (e.g., benzyl), naphthyl, pyridineamino, 9-purine-6-amino, thiazoleamino, aryloxy, arylalkyloxy, pyridyl, quinolinyl or isoquinolinyl; R₄ is hydrogen, a halogen, a phenyl or a cycloalkyl moiety and n is an integer from 3 to 10.

- 229. (Withdrawn) A method of treating cancer in a subject in need thereof by administering to said subject an effective amount of a pharmaceutical composition comprising a HDAC inhibitor or a pharmaceutically acceptable salt or hydrate thereof, and a pharmaceutically acceptable carrier or diluent, wherein the composition is administered once, twice or three times daily at a total daily dose of up to about 800 mg.
- 230. (Withdrawn) The method according to claim 229, wherein the pharmaceutical composition is administered orally.

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231. (Withdrawn) The method according to claim 230, wherein said composition is contained within a gelatin capsule.

- 232. (Withdrawn) The method according to claim 231, wherein said carrier or diluent is microcrystalline cellulose.
- 233. (Withdrawn) The method according to claim 232, further comprising sodium croscarmellose as a disintegrating agent.
- 234. (Withdrawn) The method according to claim 233, further comprising magnesium stearate as a lubricant.
- 235. (Withdrawn) The method of claim 230, wherein said composition is administered oncedaily, twice-daily or three times-daily.
- 236. (Withdrawn) The method of claim 235, wherein said composition is administered once daily at a dose of about 200-600 mg.
- 237. (Withdrawn) The method of claim 235, wherein said composition is administered twice daily at a dose of about 200-400 mg.
- 238. (Withdrawn) The method of claim 237, wherein said composition is administered twice daily at a dose of about 200-400 mg intermittently.
- 239. (Withdrawn) The method of claim 238, wherein said composition is administered twice daily three to five days per week.
- 240. (Withdrawn) The method of claim 239, wherein said composition is administered twice daily three days a week.

- 241. (Withdrawn) The method of claim 240, wherein said composition is administered twice daily at a dose of about 200 mg, three days a week.
- 242. (Withdrawn) The method of claim 240, wherein said composition is administered twice daily at a dose of about 300 mg, three days a week.
- 243. (Withdrawn) The method of claim 235, wherein said composition is administered three times a day.
- 244. (Withdrawn) The method of claim 243, wherein said composition is administered three times-daily for two consecutive weeks, followed by one week without administration of said composition.
- 245. (Withdrawn) The method according to claim 229, wherein said HDAC inhibitor is suberoylanilide hydroxamic acid (SAHA):

246. (Withdrawn) The method according to claim 229, wherein said HDAC inhibitor is pyroxamide, represented by the structure:

247. (Withdrawn) The method according to claim 229, wherein said HDAC inhibitor is represented by the structure:

$$R_3$$
 R_4 C $CH_2)n$ C R_2

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wherein R_3 and R_4 are independently a substituted or unsubstituted, branched or unbranched alkyl, alkenyl, cycloalkyl, aryl, alkyloxy, aryloxy, arylalkyloxy, or pyridine group, cycloalkyl, aryl, aryloxy, arylalkyloxy, or pyridine group, or R_3 and R_4 bond together to form a piperidine group; R_2 is a hydroxylamino group; and n is an integer from 5 to 8.

248. (Withdrawn) The method according to claim 229, wherein said HDAC inhibitor is represented by the structure:

wherein R is a substituted or unsubstituted phenyl, piperidine, thiazole, 2-pyridine, 3-pyridine or 4-pyridine and n is an integer from 4 to 8.

249. (Withdrawn) The method according to claim 229, wherein said HDAC inhibitor is represented by the structure:

$$R_1$$
 R_2
 R_4
 R_4
 R_4
 R_4
 R_4
 R_4
 R_4

wherein A is an amide moiety, R₁ and R₂ are each selected from substituted or unsubstituted aryl (e.g., phenyl), arylalkyl (e.g., benzyl), naphthyl, pyridineamino, 9-purine-6-amino, thiazoleamino, aryloxy, arylalkyloxy, pyridyl, quinolinyl or isoquinolinyl; R₄ is hydrogen, a halogen, a phenyl or a cycloalkyl moiety and n is an integer from 3 to 10.

250. (Withdrawn) A method of chemoprevention in a subject in need thereof by administering to said subject an effective amount of a pharmaceutical composition comprising a HDAC inhibitor or a pharmaceutically acceptable salt or hydrate thereof, and a pharmaceutically acceptable carrier or diluent, wherein the composition is administered once, twice or three times daily at a total daily dose of up to about 800 mg.

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251. (Withdrawn) The method according to claim 250, wherein the pharmaceutical composition is administered orally.

- 252. (Withdrawn) The method according to claim 251, wherein said composition is contained within a gelatin capsule.
- 253. (Withdrawn) The method according to claim 252, wherein said carrier or diluent is microcrystalline cellulose.
- 254. (Withdrawn) The method according to claim 253, further comprising sodium croscarmellose as a disintegrating agent.
- 255. (Withdrawn) The method according to claim 254, further comprising magnesium stearate as a lubricant.
- 256. (Withdrawn) The method of claim 251, wherein said composition is administered oncedaily, twice-daily or three times-daily.
- 257. (Withdrawn) The method of claim 256, wherein said composition is administered once daily at a dose of about 200-600 mg.
- 258. (Withdrawn) The method of claim 256, wherein said composition is administered twice daily at a dose of about 200-400 mg.
- 259. (Withdrawn) The method of claim 258, wherein said composition is administered twice daily at a dose of about 200-400 mg intermittently.
- 260. (Withdrawn) The method of claim 259, wherein said composition is administered twice daily three to five days per week.

- 261. (Withdrawn) The method of claim 260, wherein said composition is administered twice daily three days a week.
- 262. (Withdrawn) The method of claim 261, wherein said composition is administered twice daily at a dose of about 200 mg, three days a week.
- 263. (Withdrawn) The method of claim 261, wherein said composition is administered twice daily at a dose of about 300 mg, three days a week.
- 264. (Withdrawn) The method of claim 256, wherein said composition is administered three times a day.
- 265. (Withdrawn) The method of claim 264, wherein said composition is administered three times-daily for two consecutive weeks, followed by one week without administration of said composition.
- 266. (Withdrawn) The method according to claim 250, wherein said HDAC inhibitor is suberoylanilide hydroxamic acid (SAHA):

267. (Withdrawn) The method according to claim 250, wherein said HDAC inhibitor is pyroxamide, represented by the structure:

268. (Withdrawn) The method according to claim 250, wherein said HDAC inhibitor is represented by the structure:

$$R_3$$
 R_4 C $CH_2)n$ C

wherein R_3 and R_4 are independently a substituted or unsubstituted, branched or unbranched alkyl, alkenyl, cycloalkyl, aryl, alkyloxy, aryloxy, arylalkyloxy, or pyridine group, cycloalkyl, aryl, aryloxy, arylalkyloxy, or pyridine group, or R_3 and R_4 bond together to form a piperidine group; R_2 is a hydroxylamino group; and n is an integer from 5 to 8.

269. (Withdrawn) The method according to claim 250, wherein said HDAC inhibitor is represented by the structure:

wherein R is a substituted or unsubstituted phenyl, piperidine, thiazole, 2-pyridine, 3-pyridine or 4-pyridine and n is an integer from 4 to 8.

270. (Withdrawn) The method according to claim 250, wherein said HDAC inhibitor is represented by the structure:

wherein A is an amide moiety, R₁ and R₂ are each selected from substituted or unsubstituted aryl (e.g., phenyl), arylalkyl (e.g., benzyl), naphthyl, pyridineamino, 9-purine-6-amino, thiazoleamino, aryloxy, arylalkyloxy, pyridyl, quinolinyl or isoquinolinyl; R₄ is hydrogen, a halogen, a phenyl or a cycloalkyl moiety and n is an integer from 3 to 10.

271. (New) The method according to claim 1 or claim 34, wherein said composition is administered once daily at a dose of 400 mg.

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272. (New) The method according to claim 271, wherein said composition is administered every day.

- 273. (New) The method according to claim 1 or claim 34, wherein said composition is administered once daily at a dose of 300 mg.
- 274. (New) The method according to claim 273, wherein said composition is administered every day.
- 275. (New) The method according to claim 1 or claim 34, wherein said composition is administered five days a week, once daily at a dose of 300 mg.
- 276. (New) The method according to claim 1 or claim 34, wherein said composition is administered once daily at a dose of 300 mg on a schedule of 14 days out of each 21 days.